

The Use of AI in IRB Protocol Generation



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AI-Assisted IRB Submissions: Ethics, Transparency, and Oversight

The use of artificial intelligence (AI), large language models (LLMs), and similar technologies have become not only accessible, but increasingly commonplace throughout the research process. Like any new technology, the landscape is quickly evolving and changing. As an independent (Institutional Review Board) IRB we routinely review research involving AI technologies. Similarly, there has also been a rise in AI generated submissions. As many individuals familiar with these LLMs know, the writing style can be distinctly recognizable given enough experience. Some investigators disclose this assistance within the protocol while others do not. This raises both philosophical and practical questions: Is the use of AI to prepare IRB materials acceptable? Is it ethical? And should investigators disclose its use?

AI and IRB Oversight: The Regulatory Landscape

As with many issues in relation to IRBs, we first reference the regulations. There should be no surprise here that the regulations are silent on the matter. The revised Common Rule and subsequent FDA revisions of 2018 make no mention of AI, as the concept had yet to establish widescale use. To reiterate, 2 of the IRB's most foundational regulatory documents were drafted prior to the AI boom. Expanding upon this, non-Common Rule signatories certainly did not have AI ethics on their regulatory landscape prior to 2018.

Failing to find regulatory standing, the IRB evaluates departmental guidance from the FDA, as well as from HHS and their other agencies. We find loosely related guidance from the CDC which requires authors to "Fully disclose substantive uses of GenAI in your work, in accordance with requirements of your organization, funder, publisher, and any other collaborating or partner organizations". This guidance is consistent with other agencies which IRBs typically reference; they instruct investigators to comply with other requirements or they remain silent.

Case Example

One notable discussion is a case study published by the NIH Office of Intramural Research which addresses the topic directly, albeit not an official guidance. In this case study, NIH posits that authors may use AI in writing protocols, consent documents, and other documents for submission, although investigators "should not fully rely on them". Furthermore, the work confirms that disclosure of the use of AI is not mandated by the NIH, however disclosures may be required by other parties (as listed above). In essence, this case study has framed the issue as one of scientific integrity, rather than one of human subject research protection.

AI as a Research Tool: Responsibility and Oversight

The IRB takes a similar stance on the use of AI generated elements for use in human subject research. AI or LLMs are a tool available for use, however substantial use should be avoided due to issues of scientific integrity and output errors. Leaving aside the ethical implications in relation to scientific integrity, these models produce errors, and their outputs should be strictly monitored for accuracy. Naturally, the same can be said for human generated outputs, however these avert the issue of originality and integrity. In either case, the PI is responsible for both human and AI outputs and should take equal care in assuring these are ethical and compliant.

Summary

In summation, the IRB views AI as a tool that may be used by the PI, similar to many others that are available (spell check, reference management, etc.). As such, the IRB will remain focused on its intended purpose: protecting the rights, safety, and welfare of participants. It is the IRB's opinion that if the use of AI or human outputs do not adversely affect these core tenants, the use of AI or other tools are deemed acceptable by the IRB. Furthermore, if use of AI enhances submissions, thereby elevating participant protections, then its use should be more widely accepted. It is the responsibility of the PI to disuse or disclose use of AI to comply with any requirements external to the IRB.

As always, if you have questions about AI use in IRB submission, or any other IRB-related issues, please feel free to contact me at **clayton.gillespie@salusirb.com**

References

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2. National Institutes of Health, Office of Intramural Research. (2025). Case studies: Facilitator's guide (Rev. Dec. 9, 2025). U.S. Department of Health and Human Services. https://oir.nih.gov/system/files/media/file/2025-12/case_studies-2025-facilitators-revised-2025_12_09.pdf